K070102

9. Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

SOPRO
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FRANCE

FEB 2 0 2007

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Contact Person: Steve Salesky
SOPRO
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
Tel: 800 289-6367 Ext. 40
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E-mail: steve.salesky@us.acteongroup.com

Date Prepared: January 5, 2007

B. Device Identification

Classification Name: Laparoscope, General & Plastic Surgery

Common Usual Name: Laparoscope and accessories

Proprietary Name: SOPRO 162 camera

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
SOPRO 61D	SOPRO	K031593	September 16, 2003

The SOPRO 162 is substantially equivalent to the predicate device by SOPRO, the SOPRO 61D (K031593) previously cleared by the FDA and currently marketed.

D. Device Description

The SOPRO 162 is a high resolution, digital processing camera system utilizing a CCD image sensor. It provides high quality images with excellent resolution and color contrast. Its contour enhancer gives the impression of a 3D image. This makes the camera a multidisciplinary tool.

The SOPRO 162 is a modification of the SOPRO 61D previously cleared on 510(k) K031593. The modifications are the addition of a USB2 port option, the addition of a foot control that allows for the freezing of an image when using the

USB2 port option, and the addition of a stand-by board (electronic board). The SOPRO 162 requires the operator to initially turn on a master switch before turning on the unit with a button on the front panel.

E. Intended Use

The SOPRO 162 camera is intended to be used by qualified physicians in general and plastic surgery to provide access, illumination and allow observation or manipulation of body cavities, hollow organs, and canals.

F. Substantial Equivalence

The SOPRO 162 camera and the predicate device, SOPRO 61D camera (K031593) are both laparoscopes and accessories for use in general and plastic surgery by qualified physicians. Differences that exist between the devices relating to technical specifications, performances and intended use are minor and do not affect the safety and effectiveness of the SOPRO 162.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2007

SOPRO
% ACETON, Inc.
Mr. Steve Salesky
Quality Manager
124 Gaither Drive, Suite 140
Mt. Laurel, New Jersey 08054

Re: K070102
Trade/Device Name: SOPRO 162 Camera
Regulation Number: 21 CRF 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 5, 2007
Received: January 10, 2007

Dear Mr. Salesky:

This letter corrects our substantially equivalent letter of February 20, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: **SOPRO 162 Digital Endoscopy Camera**

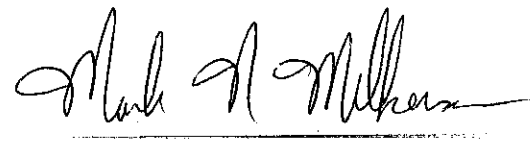
Indications for Use:

"Providing access, illumination and allow observation or manipulation of body cavities, hollow organs, and canals."

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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